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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,381	03/19/2004	Scott Edward Osborne	7892C	7237

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EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT PAPER NUMBER

1615

DATE MAILED: 04/19/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/804,381

Applicant(s)

OSBORNE ET AL.

Examiner

Lakshmi S. Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 February 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4-7-06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt of amendment, claims, remarks dated 2-3-06 and IDS dated 4-7-06 is acknowledged.

Claims 1-20 are pending in the instant application.

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2-3-06 has been entered.

The following rejection of record has been maintained:

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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Claims 1-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,716,441. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons: The patented claims directed to an article and a method of effectively delivering one or more skin care actives including chitosan, barrier protectant and release agents. Instant claims recite a release composition comprising chitosan as an active agent, a release agent and a barrier protectant such as paraffin wax. Thus, instant claims constitute a species of the broadly recited active agents and barrier protectant. While instant claims are generic to a release agent, the patented claims also recite the release agents that are encompassed by instant release agents. Instant claims also recite an article comprising the claimed composition and accordingly, it would have been within the scope of a skilled artisan at the time of the instant invention to prepare a release composition comprising chitosan as active agent and paraffin wax as the barrier protectant, together with the release agents from the patented composition also prepare an article comprising the release agent with an appropriate dispensing means.

The following is anew rejection:

Claim Rejections - 35 USC § 112

2. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants state that the specification supports paraffin wax as having about 16-50 carbon atoms. However, Instant claims 1, 14 and 17 recite 16 to about 15 carbon atoms, which appears to be a typographical error. However, a clarification is requested.

Claim Objections

3. Claims 3, 4, 10 and 20 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Instant claim 3, dependent from claim 1, recites skin active agents in a markush language. However, claim 1 is limited to chitosan as an active.

Claim 4 is dependent on an improperly dependent claim and is hence objected.

Claim 10, dependent from claim 1, recites barrier protectant in a markush language. However, claim 1 is limited to paraffin wax as a barrier protectant.

Similarly claim 20, dependent from claim 17, recites barrier protectant in a markush language. However, claim 17 is limited to paraffin wax as a barrier protectant.

Claim Rejections - 35 USC § 103

4. Claims 1-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,643,588 to Roe in view of US 6,562,802 to Johansson et al.

Roe teaches a diaper (reads on the instant article), comprising a lotioned topsheet, wherein the lotion composition is a semisolid or a solid at 20degrees C and is adapted to be transferred to the wearer's skin (as claimed, col. 9-10). The lotion of Roe comprises emollients (read on claimed protectants) such as petrolatum, fatty acid ester, fatty alcohols, polysiloxanes, waxes etc (col. 11-12); immobilizing agents (cols. 13-16), surfactants (col. 16-18), including those having HLB value in the claimed range. For paraffin wax, see example 6 and claim 19. Roe further teaches incorporating active agents such as pharmaceutical or antibacterial active agents in the lotion, particularly therapeutic agents (Col.18). Roe fails to teach the claimed chitosan.

Johansson teaches topical active barrier cream compositions in the form of gel comprising chitosan, urea, lactic acid, glycerol, cetylstearyl alcohol, paraffin liquid, polyoxyethylene-2-stearyl-ether and saline (col. 16, lines 64-67; example I in col. 17). The components urea, lactic acid, paraffin liquid and polyoxyethylene-2-stearyl-ether read on the claimed skin protectant, pH control agent, and barrier protectant and release agent respectively. Johansson teaches skin composition containing chitosan in the form of cream, lotion or gel and suggests the addition of an amine- containing polymer, chitosan, for successful binding of antiallergenic substances such as EDTA (meets limitation of claim 4)(col. 8). Johansson teaches that the chitosan polymer forms a barrier protection and prevents contact of skin with the allergens or other irritants.

Therefore, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to add chitosan and anti-allergens such as EDTA of Johansson to the lotion composition applied to a diaper (of Roe) because Johansson suggests that chitosan has superior features to make it a skin or mucus membrane protector when combined with an anti-allergen and is very effective in protecting skin during therapeutic treatments with anti-viral, anti-bacterial treatment or for UV protection (col. 6 and 8).

Roe and Johansson suggest various percentages or amounts of the claimed components that fall within the claimed ranges and accordingly, optimizing the amounts of the same so as to achieve the optimum release of the active agent to skin and at the same time provide barrier protection to skin from irritants or allergens would have been within the scope of a skilled artisan.

5. Claims 1-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-32 of U.S. Patent No. 6,153,209. Although the conflicting claims are not identical, they are not patentably distinct from each other because of the following reasons: The patented claims directed to an article and a method of effectively delivering one or more skin care actives and is generic to various skin active agents, surfactants, emollients, etc., all of which are claimed in the instant application. The patented claims also recite the claimed chitosan, emollients, surfactants, barrier protectants (claimed as immobilizing agents) etc., thus anticipating instant claims.

Claims directed to an invention not patentably distinct from claims 1-32 of commonly assigned US 6,153,209.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP Chapter 2300). Commonly assigned 6,153,209, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications pending on or after December 10, 2004.

Response to Arguments

Applicant's arguments filed 2-3-06 have been fully considered but they are not persuasive.

Applicants stated that upon indicating allowable subject matter, a terminal disclaimer would be filed. However, at this time no claim is allowable and hence the double patenting rejection has been maintained.

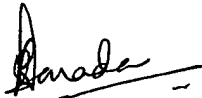
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Applicants' arguments with respect to the rejections of claims under 35 USC 103(a) set forth in the previous action, are moot in view of the new grounds of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala
Examiner
Art Unit 1615

April 13, 2006